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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,390	12/03/2001	Stephen M. Zappala	16865-00011	6989
7590	02/24/2005		EXAMINER	
Jenifer E. Haeckl, Esq. Mirick, O'Connell, DeMallie & Lougee, LLP 1700 West Park Drive Westborough, MA 01581-3941			EVANISKO, GEORGE ROBERT	
		ART UNIT	PAPER NUMBER	
			3762	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	<i>[Signature]</i>
	10/005,390	ZAPPALA	
	Examiner George R Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 December 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7 and 9-14 is/are pending in the application.
 4a) Of the above claim(s) 7 and 14 is/are withdrawn from consideration.
 5) Claim(s) 1-3,5,6 and 9-11 is/are allowed.
 6) Claim(s) 4,12 and 13 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 7 and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/10/04.

This application contains claims 7 and 14 drawn to an invention nonelected with traverse in the paper filed 5/10/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the power source and pulse generating member in the shell, and means for enabling must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original specification is the battery having a high impedance of 800 to 2000 ohms. Only the tissue on page 9 of the specification talks about an impedance of 800 to 2000 ohms. (It is suggested to state "wherein said power source member comprises a battery".)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, “adapted to stimulate said patient’s neurovascular bundle have an impedance” is vague and seems not to be worded correctly.

In claim 12, “as implanted at the suprapubic level” is vague and sounds as if the system is claiming a connection to the body. System claims can not claim connection to the body. It is suggested to use “adapted to be implanted at the...”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Krakovsky.

Krakovsky discloses the claimed invention using 2.5-5 Volt pulses, that the pulse parameters (height, frequency, etc) can be changed for each individual patient by testing (column 3), and the use of other electrodes for connecting to the nerves/muscles (column 5 and 6). In addition, Krakovsky teaches that the device, 30, is implanted and therefore has a biocompatible shell (in the alternative, see the rejection below), teaches that the unit is controlled by an external start button (figure 4) and shows the programmable circuit in between the battery and pulse generator (figure 3) and therefore has a means for enabling the patient to activate the power source and pulse generator, and Krakovsky inherently is capable of being implanted in a pocket of a patient’s abdominal wall and the electrode at the suprapubic level since he provides an implantable device and implantable leads that can be implanted in the body.

Krakovsky does not teach the electrode tip comprised of an indifferent material, and, in the alternative to the discussion above, the circuitry housed in a biocompatible shell, and a means for enabling the patient to activate the power source and pulse generator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable device as taught by Krakovsky, with an electrode tip comprised of an indifferent material, such as stainless steel or platinum, the circuitry housed in a biocompatible shell, and a means for enabling the patient to activate the power source and pulse generator since it was known in the art that implantable devices use: an electrode tip comprised of an indifferent material, such as stainless steel or platinum, that is biocompatible and/or will not substantially degrade the electrodes due to the pulses being delivered through the electrode; the circuitry housed in a biocompatible shell to provide a biocompatible housing that does not degrade in the body; and a means for enabling the patient to activate the power source member and pulse generator to reduce power drain when the generator is not being used and extend the battery life of the generator

Claims 13 is rejected under 35 U.S.C. 103(a) as obvious over Krakovsky et al. Krakovsky uses 2.5-5 volt pulses at a frequency of 2 Hz which is about the claimed “about 10 Hz” high frequency pulses of claim 13.

In the alternative, Krakovsky discloses the claimed invention using 2.5-5 Volt pulses and that the pulse parameters (height, frequency, etc) can be changed for each individual patient by testing (column 3) but does not disclose expressly the use of high frequency pulses of about 10-40 Hz. Krakovsky provides a clear suggestion that the pulse height and frequency can be

modified to determine the appropriate stimulation parameters based on the particular patient and place of stimulation. The determination of the most appropriate pulse height and frequency, such as about 10-40 Hz and 1 to 5.5 V, by routine experimentation would, therefore, be *prima facie* obvious to one having ordinary skill in the medical art.

Allowable Subject Matter

Claims 1-3, 5, 6, and 9-11 are allowed.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. Ardito et al, Meloy et al, and Lue et al are three teachings of many showing a means for enabling the patient to activate the power source member and pulse generator, the use of 10-40 Hz and 1 to 5.5 V pulses, and the use of a biocompatible shell, respectively. In addition, as seen in Ardito et al (one teaching of many), two electrodes are provided on the lead to provide a bipolar lead, and one of the electrodes is inherently the indifferent/common/return electrode since the pulses are delivered between the two electrodes.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko
Primary Examiner
Art Unit 3762

2/21/5

GRE
February 21, 2005